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PATENT SPECIFICATION

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(54) IMPROVEMENTS IN AND RELATING TO MEDICAL EQUIPMENT

(71) We, WILKINSON SWORD LIMITED, a British Company, of Sword House, Totteridge Road, High Wycombe, Buckinhamshire, HP13 6EJ (formerly of Sword Works, Southfield Road, London, W.4), do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The invention relates to cryogenic probes such as for use in human and animal surgery for example.

According to the invention, there is provided a hand-held cryogenic probe, comprising means for receiving a sealed capsule containing a cryogenic fluid under pressure, means for causing relative movement between a needle tube and the capsule whereby the needle tube ruptures the seal and conveys the exiting fluid to a valve, and a second tube for conveying the fluid from and under control of the valve to an expansion chamber in heat-conducting relationship with a probe tip whereby expansion of the fluid in the chamber cools the tip by the Joule-Thomson effect, the fluid resistance of the second tube being sufficiently high that substantially all of the fluid expansion occurs in the said expansion chamber and there is substantially no pressure drop across the valve means.

According to the invention, there is further provided a cryogenic probe, comprising a body having two oppositely disposed screw-threaded extremities through which a needle tube and a second tube respectively inwardly extend to a valve manually operable from externally of the body to connect and disconnect the inner ends of the said tubes, a screw-threaded cap for receiving a sealed capsule containing a cryogenic fluid under pressure and for threadably engaging the said extremity through which the needle tube extends so as to form therewith a chamber containing the capsule whereby tightening of the cap presses the needle tube through the capsule to allow escape of the fluid along the tube, a screw-threaded expansion chamber for threadably engaging the other extermity and into the distal end of which the second tube discharges the said fluid under control of the valve so as to cool the distal end by the Joule-Thomson effect, and a probe tip mounted on and in good thermally conductive relationship with the distal end of the expansion chamber, the relative diameters and fluid resistances of the two tubes being such that substantially all of the expansion of the fluid takes place in the expansion chamber and there is substantially no pressure drop across the valve.

A hand-held cryogenic probe for use in cataract and similar surgery and embodying the invention will now be described with reference to the accompanying diagrammatic drawing which is a longitudinal cross-section through the probe.

The probe comprises a cylinder 5, one end of which is closed and the other end of which is open and internally threaded for releasable attachment to a body 6. The body 6 contains a re-entrant portion 8 into which the end of a fixed needle tube 10 projects, the other of the needle tube communicating with a hollow chamber 12. A further, longer, needle tube 14, having an inner diameter of say 5 to 8 thousandths of an inch, extends outwardly from the opposite side of the chamber 12 and into an expansion chamber 16. The expansion chamber 16 is welded to a collar 18 which is threaded to engage with a nose piece 20 on the body 6. Passages 22, 24 are provided to connect the interior of the expansion tube 16 with the surrounding atmosphere. The tip 26 of the expansion

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chamber 16 is made of a material, such as copper or silver, having good heat conduction and compatibility with human tissue and is suitably formed for ease of placement and adhesion to the lens of the eye. The probe tip 26 can instead be constructed as a miniaturised heat pipe. A heat pipe gives a much greater thermal conductivity than solid conductors (possibly, one thousand times as great as copper) and its operation involves the evaporation of a liquid at the region to be cooled and its condensation at a physically separated region where the heat can be easily removed, see United States Patent Specification No. 2350348. The system is a continuously recirculating one, using a porous wick. Advantageously, the pipe 14 and the rest of the structure, apart from the tip 26, has a low thermal conductivity.

The chamber 12 is defined by a through-bore in the body 6, and by two rubber (or similar material) diaphragms 28 and 30. The periphery of each diaphragm is held in position in the body 6 by means of respective plugs 32, 34. The plug 34 has a bore through it, and the stem 36 of a press button 38 slidingly extends into this bore and is fixed to the centre of the diaphragm 30.

A valve member 40 is a close sliding fit within the chamber 12 and has an asymmetrically positioned through-bore 42.

Therefore, downward (as viewed in the Figure) pressure on the button 38 pushes the diaphragm 30 and the valve member 40 downwards, against the force of a compression spring 44, until the asymmetrical bore 42 becomes aligned with the two needle tubes 10 and 14. When downward pressure on the button 38 is released, the spring 44 forces the valve member 40 upwards again into the position illustrated, thus cutting off ccommunication between the needle tubes 10 and 14.

In use of the probe, the cylinder 5 is removed and a capsule 46 containing CO_2 is inserted in the manner shown. The cylinder 5 is then placed and screwed on to the body 6, whereupon the protruding end of the needle tube 10 pierces a diaphragm seal in the end of the capsule 46, causing gas under pressure to flow along the tube 10. When the button 38 is pressed downwards, the valve member 40 connects the tubes 10 and 14 in the manner explained, and the gas under pressure exits through the distal end of the tube 14. A very small orifice at the distal end of the tube 14 ensures that substantially all of the expansion of the exiting gas to atmospheric pressure takes place adjacent the tip 26 of the expansion tube 16. The resultant Joule-Thomson effect rapidly cools the tip 26. This cooling effect enables the tip 26 of the probe to become adhered to the patients' lens tissue, and the lens can thereby be removed. The expanding gas is vented to the atmosphere through the passages 22 and 24.

If the surgeon desires to release the attached piece of tissue, he merely has to release the button 38 so as to cut off the flow of gas. The tip 26 rapidly warms up and thus releases the tissue. Instead, the valve member - 40 may have a second through-bore of smaller cross-sectional area than the orifice at the end of the tube 14, and by allowing the valve member 40 to move into a position in which this second bore becomes aligned with the tubes 10 and 14 (with the aid of a suitable detent mechanism operating on the stem 36, for example), the primary gas expansion can be caused to occur at the valve member 40 instead of the distal end of the tube 14; thus, the temperature at the tip 26 of the expansion chamber 16 will increase.

The valve can be made very light in operation (requiring only a few grams force for example) so as not to disturb or move the probe as a whole when operated.

It will be noted that the diameterl of the tube 14 is small (of the same order as that of the bore 42 and tube 10), and hence, during normal (cooling) operation, the majority of the pressure drop in the gas occurs at the distal end of the tube 14. The pressure drop across the valve is therefore small and leakage problems are thereby minimized. The use of the flexible diaphragm 30 eliminates sealing problems between the button 38 and the valve member 40. The diaphragm 28 could be dispensed with, but its provision is advantageous in that it reduces the dead volume of the chamber 12 (into which leaking gas could expand and cool), and also facilitates manufacture and assembly.

The CO_2 capsule 46 can be of the type sold under the Trade Mark "Sparklets" by the British Oxygen Company Limited and is thus readily available making the probe inexpensive to use.

The cylinder 5 is provided with a vent 48 to prevent accumulation of gas in the cylinder 5 in the event of a leak between the capsule 46 and the end of the needle tube 10.

The probe described is completely portable and requires no attaching tubes or the like for feeding a gas supply from a separate source: such tubes may form a considerable hazard in operating theatres, and they also make the necessary handling delicacy difficult to achieve.

The valve mechanism described may be replaced by other suitable mechanism. For example, the valve member 40 could be replaced by a small piece of magnetic

material containing a hole or through-bore. By rotating or moving an externally positioned magnetised member, the internal magnetic piece can be made to move between a position in which its through-hole or bore allows gas flow and a position in which the gas flow is blocked. Such an arrangement obviates the need for gas sealing. The externally mounted magnetised member could be an electromagnet or permanent magnet.

The passages 22 and 24 should be arranged to exhaust well clear of the patient, and it might be desirable to connect them, by means of interior passageways or the like, to exhaust positions more removed from the probe tip 26 than those shown.

When a particular surgical operation has been completed, the valve can be moved to the closed position, and the expansion chamber 16 (or just the tip if so arranged) can then be removed and sterilised, and then refitted for use in a further operation with the remaning gas in the capsule 46.

The whole structure can be made sufficiently inexpensively to be disposable as a unit. Instead or in addition, it can be constructed so as to be sterilisable as a unit, as in an autoclave.

WHAT WE CLAIM IS:

1. A hand-held cryogenic probe, comprising means for receiving a sealed capsule containing a cryogenic fluid under pressure, means for causing relative movement between a needle tube and the capsule whereby the needle tube ruptures the seal and conveys the exiting fluid to a valve, and a second tube for conveying the fluid from and under control of the valve to an expansion chamber in heat-conducting relationship with a probe tip whereby expansion of the fluid in the chamber cools the tip by the Joule-Thomson effect, the fluid resistance of the second tube being sufficiently high that substantially all of the fluid expansion occurs in the said expansion chamber and there is substantially no pressure drop across the valve.

2. A probe according to claim 1, in which the means for receiving the said capsule comprises a recess for receiving a sealed end of the said capsule, the said needle tube extending into the recess through the base thereof and the recess having a threaded wall for receiving a cap which, when screwed home, presses the sealed end of the capsule and the needle tube together so that the tube ruptures the sealed end of the capsule.

3. A cryogenic probe, comprising a body having two oppositely disposed screw-threaded extremities through which a needle tube and a second tube respectively inwardly extend to a valve manually operable from externally of the body to connect and disconect the inner ends of the said tubes, a screw-threaded cap for receiving a sealed capsule containing a cryogenic fluid under pressure and for threadably engaging the said extremity through which the needle tube extends so as to form therewith a chamber containing the capsule whereby tightening of the cap presses the needle tube through the capsule to allow escape of the fluid along the tube, a screw-threaded expansion chamber for threadably engaging the other extremity and into the distal end of which the second tube discharges the said fluid under control of the valve so as to cool the distal end by the Joule-Thomson effect, and a probe tip mounted on and in good thermally conductive relationship with the distal end of the expansion chamber, the relative diameters and fluid resistances of the two tubes being such that substantially all of the expansion of the fluid takes place in the expansion chamber and there is substantially no pressure drop across the valve.

4. A probe according to claim 2 or 3, in which the said cap has an exhaust port open to atmosphere for venting the interior of the cap.

5. A probe according to any preceding claim, in which the said probe tip is constructed to have a relatively high thermal conductivity and the adjacent structure supporting the tip is constructed to have a relatively low thermal conductivity.

6. A probe according to any preceding claim, in which the probe tip is constructed as a miniature heat pipe.

7. A probe according to any preceding claim, in which the valve comprises a hollow valve chamber which is sealed except for two openings substantially opposite each other and respectively communicating with the needle tube and the second tube, and a valve member having a through-bore and positioned in the chamber so as to be movable between a position in which the through-bore becomes aligned with the said openings so as to connect the two tubes together and a position in which the through-bore is out of the said alignment and the member blocks communication between the two tubes.

8. A probe according to claim 7, in which the valve chamber is defined in part by a flexible wall, and including a member manually movable from externally of the probe for applying a force to the valve member through the flexible wall to move it between its two said positions.

9. A probe according to claim 8, including a second flexible wall for the valve chamber and opposite to the first-mentioned flexible wall, both the said walls

being in contact with the valve member to minimise the free space in the valve chamber.

10. A probe according to claim 7, in which the valve member is magnetic or magnetised and including means external of the valve chamber and magnetically linked to the valve member and manually movable so as to move the valve member between its two said positions by magnetic interaction therewith.

11. A probe according to any preceding claim, including means for discharging expended cryogenic fluid from the expansion chamber at a position on the probe at the opposite end thereof from the probe tip.

12. A probe according to any preceding claim, in which the probe tip is removable and sterilisable.

13. A probe according to any preceding claim, and constructed so as to be autoclavable as a unit.

14. A hand-held self-contained cryogenic probe, substantially as described with reference to and as illustrated in the accompanying drawing.

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